Thermogard XP®



Intravascular Temperature Management System



Value Procurement Insights

for high-quality targeted temperature management



Sudden out-of-hospital cardiac arrest (OHCA) is the third leading cause of death in Europe.¹ Every year approximately 275,000 cases of cardiac arrest occur outside of a hospital setting in Europe,¹ of which about 8% survive. Approximately 200,000 cardiac arrests occur each year in hospitals, and 22% of those patients survive.² Of those patients who do survive, many are discharged with severe cognitive impairment, leading to a lifetime of debilitation, multiple readmissions, and expensive aftercare.

Recovery after cardiac arrest

Timely restoration of blood flow after the onset of cardiac arrest (CA) is critical to survival, and studies show that mild therapeutic hypothermia, also referred to as induced hypothermia (IH) or targeted temperature management (TTM), reduces inflammation and other harmful processes that occur immediately following reperfusion.³

In addition, reduced time from the onset of arrest or initiation of therapeutic reduction of core body temperature to achieving moderate hypothermia is associated with significantly better outcomes.^{4,5} In patients resuscitated from CA, decreasing the time to target temperature appears to be associated with better survival rates.

High-quality targeted temperature management (HQ TTM), which includes fever control, therapeutic hypothermia (TH), and warming, has been shown to improve outcomes, reduce complications, and deliver a beneficial economic impact on society and hospitals.⁶⁻¹¹

Major medical societies recommend targeted temperature management as the standard of care for patients after cardiac arrest. 12-14

- American Heart Association (AHA)
- European Resuscitation Council (ERC)
- European Society of Intensive Care Medicine (ESICM)
- International Liaison Committee on Resuscitation (ILCOR)



Why Intravascular Temperature Management?

Intravascular temperature management has shown significantly better neurological outcomes compared to surface cooling methods in patients after cardiac arrest.⁶

Clinical Parameters	Intravascular	Surface	
Reaching Target Temperature	100% reached target temperature ¹⁵	29% of patients did not reach target temperature. ¹⁶	
Target Temperature Maintained (± 0.2°C)	Superior: 97% of time in range ⁸	Poor: 49% of time in range ⁸	
Time to Target Temperature	Rapid: 45 minutes	Slow: 240 minutes ¹⁷	
Target Temperature Overshoot (<32°C)	0%15	34%17	
Time from Event to Start of Cooling	65 minutes ¹⁸	60 minutes ¹⁸	
Shivering	4% rate of shivering.9 May require less sedation and lower doses of paralytics.19	85% rate of shivering. ²⁰ May require higher doses of paralytics. ¹⁹	
Nursing Time	Minimal: Set temperature and device adjusts automatically. Enables more focus on other aspects of patient care. ²¹	Extensive: requires management of temperature overshoot/undershoot, ²² pads, and shivering	
Patient Eligibility Patients with spinal injuries Patients with skin issues Patients on multiple vasopressors Conscious patients	Yes Yes Yes Yes	No ²³ No ²³ No ²³ No ²³	
Patient Access	Unhindered	Limited: at least 40% ²³ of the patient is covered with pads and tubing	
Adverse Events	Risk of DVT is no greater than a standard CVC ¹⁸	Potential for skin injuries ²⁴²⁶	
Central Venous Catheter (CVC) Requirement	Integrated: CVC integral to ZOLL catheter design	Additional: Separate CVC required ²¹	

IVTM IMPROVES PATIENT OUTCOMES

The Thermogard XP® System





IVTM catheters feature:

- Triple-lumen central venous catheter (CVC) functions, including medication delivery, blood draw, and central venous pressure monitoring
- Catheter kits, which include accessories needed for placement
- Hydrophilic coating with heparin
- Radiopaque body, tip, and marker band to ensure proper placement in the vessel

All IVTM catheters are MRI-compatible

Insertion sites:

- Internal jugular (IJ)
- Subclavian (S)
- Femoral (F)

UPPER-BODY CATHETERS					
Catheter Name	Solex 7™	Cool Line®			
Dwell Time	7 Days	7 Days			
Cooling Power (Watts) with TGXP	144	74			
Warming Power (Watts) with TGXP	38	21			
Insertion Site	Subclavian Internal Jugular	Subclavian Internal Jugular			
Outer Diameter (OD) at Insertion Site	9.3 F	9.3 F			
Length	20 cm	22 cm			

LOWER-BODY CATHETERS				
Catheter Name	Quattro®	lcy®	Cool Line®	
Dwell Time	4 Days	4 Days	7 Days	
Cooling Power (Watts) with TGXP	173	139	74	
Warming Power (Watts) with TGXP	48	38	21	
Insertion Site	Femoral	Femoral	Femoral	
Outer Diameter (OD) at Insertion Site	9.3 F	9.3 F	9.3 F	
Length	45 cm	38 cm	22 cm	

With ZOLL's intravascular temperature management technology, customers are purchasing more than just a device:



ZOLL's team of clinical application specialists trains customers on the device and its usage as well as on the latest clinical data.



ZOLL's **Technical Service** team helps protect your investment by providing best-in-class service programs that support long lifecycles for your high-quality temperature management system, and the most up-to-date software.



ZOLL's **Data Analytics** helps improve patient outcomes through data-driven results. You need to see your results in order to measure performance. Download raw data from Thermogard XP with no risk to patient identifiers. Our clinical consultants will review and interpret each case with you to support you in optimizing patient flow.



By investing in continuous product improvements, ZOLL enables its customers to follow new trends with existing devices. We continuously work on updating our heat exchange catheter portfolio for even better performance in existing and new indications. ZOLL's patented intravascular temperature management technology is not used only for TTM in patients with brain damage after acute ischemic encephalopathy, but also in clinical trials for ischemic stroke²⁷ and acute myocardial infarction.²⁸

Adding value to your patient care

Thermogard XP® reaches and maintains target temperature within \pm 0.2°C 100% of the time.^{6,8-11,15,29}



WHO BENEFITS FROM IVTM?







The patient: Improves chance of full recovery of heart and brain

Patients treated with IVTM have a better chance of neurological survival,⁶ less need for sedation and relaxation,³⁰ and can be mobilized earlier due to CVC as TTM treatment

IVTM can be used on patients with fragile skin or skin damage, diabetics, and patients with steroid history.³¹

Interventional cardiologist: Better tools = better outcomes

With early access to the cardiac arrest patient, the interventionist provides PCI and induces TTM. They actively affect patient survival by starting TTM early, while maintaining full patient access for intervention and CPR in the case of re-arrest ⁴

Intensivist: Provides precise therapy control

IVTM enables the intensivist to precisely manage induction and maintenance of TTM and controlled, slow rewarming followed by fever prevention.

All ZOLL heat exchange catheters double as a 3-lumen CVC and provide additional control for vasopressor drug usage.







Intensive care nurse: Manage patients, not machines

Using IVTM for targeted temperature management:

- enables nurses to auto-control patient temperature precisely
- provides nurses unhindered patient access for treatment and care
- supports nurses' ability to mobilize patients early
- offers nurses an up to 74% reduced TTM-related nursing time and liberates them to other important work⁷

Biomedical technicians: Standardized care, topnotch tech support

IVTM allows biomeds to standardize TTM for different indications throughout various departments in the hospital.

ZOLL's ExpertCare Technical Service provides first-hand technical support as well as preventive maintenance and repair as needed.

Infection control: Sterile systems for no-worry infection prevention

Using glycol as heat exchange fluid inside the cooling bath infection control eliminates concerns about water-based heater-cooler devices, which are well-known for contamination

The extended 9-foot Start-Up Kit provides healthcare professionals physical distancing when treating infectious patients.

IVTM is cost-effective³²

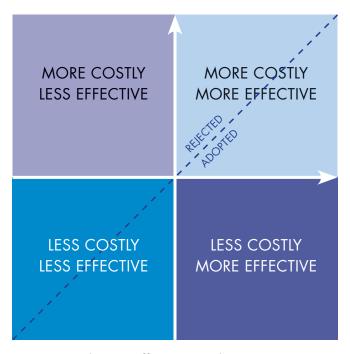


In this study, we found that the IVTM method is likely to be the most cost-effective strategy among current temperature management procedures for post-resuscitation care.³²

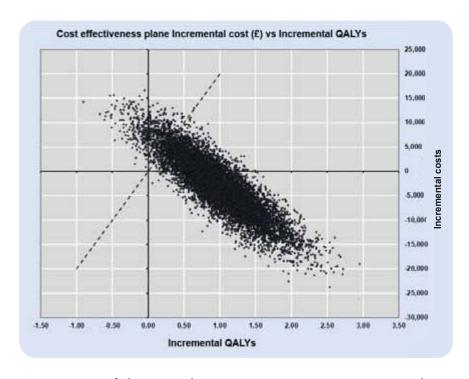
In a simulated cohort of 1,000 patients who require TTM post cardiac arrest, the Thermogard XP resulted in direct cost savings of £2,339 and £2,925 (per patient) when compared with Blanketrol III and Arctic Sun 5000 respectively, and a gain of 0.98 QALYs over the patient lifetime.³²



Enabling better clinical outcomes and reducing costs



The cost-effectiveness plane

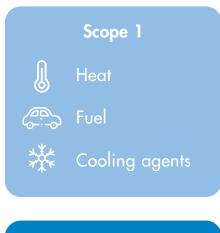


Comparison of Thermogard XP versus Arctic Sun 5000: Intravascular temperature management with Thermogard XP is less costly and more effective compared to surface cooling with Arctic Sun 5000.³²

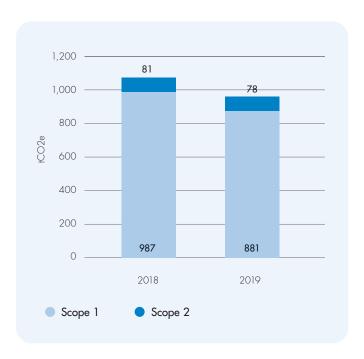
Care for People, Care for Earth

ZOLL understands that sustainability is a critical corporate responsibility in the fight against climate change. Accordingly, it is taking an active role in efforts to reduce its corporate carbon footprint (CCF). The CCF value reflects the sum of all climate-relevant emissions associated with a corporation.

As shown in the figures below, ZOLL succeeded in reducing its CCF in Scope 1 and Scope 2 by 10.2% between 2018 and 2019. This data reflects emissions from five European ZOLL facilities: Austria, Germany, France, Netherland, and UK.







Note: Manufacturing is done in the US and is not included in this analysis.





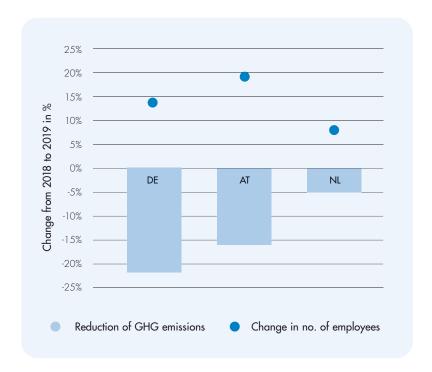
2018 CCF = Driving a car around the world 81 times2019 CCF = Driving a car around the world 75 times

The compensation for this CCF are 79,200 trees or 90 ha forest for one year.



Despite an increase in the number of employees, three European ZOLL sites (Germany, Austria, and Netherlands) succeeded in reducing greenhouse gas (GHG) emissions between 2018 and 2019.

- Germany (DE)
- Austria (AT)
- Netherland (NL)



To achieve precise and accurate TTM, two issues are crucial: the use of sedatives/analgesics and the choice of device.³⁴

References:

- Gräsner J-T, Lefering R, Koster RW, Masterson S, Böttiger BW, Herlitz J, et al. EuReCa ONE-27 Nations, ONE Europe, ONE Registry: A prospective one month analysis of out-of-hospital cardiac arrest outcomes in 27 countries in Europe. Resuscitation. 2016;105:188-95.
- ² Girotra S, Nallamothu BK, Spertus JA, Li Y, Krumholz HM, Chan PS. Trends in Survival after In-Hospital Cardiac Arrest. N Engl J Med. 2012 Nov
- ³ Schneider A, Albertsmeier M, Böttiger BW, Teschendorf P. Postreanimationssyndrom: Rolle der Entzündung nach Herz-Kreislauf-Stillstand. Anaesthesist. 2012 May;61(5):424-36.
- $^{\rm 4}$ Wolff B, Machill K, Schumacher D, Schulzki I, Werner D. Early achievement of mild therapeutic hypothermia and the neurologic outcome after cardiac arrest. Int J Cardiol. 2009 Apr; 133(2):223-8.
- ⁵ Sendelbach S, Hearst MO, Johnson PJ, Unger BT, Mooney MR. Effects of variation in temperature management on cerebral performance category scores in patients who received therapeutic hypothermia post cardiac arrest. Resuscitation. 2012 Jul;83(7):829-34.
- ⁶ Bartlett ES, Valenzuela T, Idris A, Deye N, Glover G, Gillies MA, et al. Systematic review and meta-analysis of intravascular temperature management vs. surface cooling in comatose patients resuscitated from cardiac arrest. Resuscitation. 2020 Jan; 146:82-95.
- ⁷ Deye N, Cariou A, Girardie P, Pichon N, Megarbane B, Midez P, et al. Endovascular Versus External Targeted Temperature Management for Patients With Out-of-Hospital Cardiac Arrest: A Randomized, Controlled Study. Circulation. 2015 Jul 21;132(3):182-93
- $^{\rm 8}$ Hoedemaekers CW, Ezzahti M, Gerritsen A, van der Hoeven JG. Comparison of cooling methods to induce and maintain normo- and hypothermia in intensive care unit patients: a prospective intervention study. Crit Care Lond Engl. 2007;11(4):R91.
- ⁹ Diringer MN. Treatment of fever in the neurologic intensive care unit with a catheterbased heat exchange system: Crit Care Med. 2004 Feb;32(2):559-64.
- ¹⁰ Sonder P, Janssens GN, Beishuizen A, Henry CL, Rittenberger JC, Callaway CW, et al. Efficacy of different cooling technologies for therapeutic temperature management: A prospective intervention study. Resuscitation. 2018 Mar; 124:14-
- 11 Horn CM, Sun C-HJ, Nogueira RG, Patel VN, Krishnan A, Glenn BA, et al. Endovascular Reperfusion and Cooling in Cerebral Acute Ischemia (ReCCLAIM I). J Neurointerventional Surg. 2014 Mar;6(2):91-5.
- 12 Panchal AR, Bartos JA, Cabañas JG, Donnino MW, Drennan IR, Hirsch KG, et al. Part 3: Adult Basic and Advanced Life Support: 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2020 Oct 20;142(16_suppl_2).
- ¹³ Nolan JP, Sandroni C, Böttiger BW, Cariou A, Cronberg T, Friberg H, et al. European Resuscitation Council and European Society of Intensive Care Medicine Guidelines 2021: Post-resuscitation care. Resuscitation. 2021 Apr; 161:220-69.
- ¹⁴ Nolan JP, Maconochie I, Soar J, Olasveengen TM, Greif R, Wyckoff MH, et al. Executive Summary: 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations. Circulation. 2020 Oct 20;142(16_suppl_1).
- 15 Maekawa T, Kaneda K, Tsuruta R, Kuroda Y, Nagao K, Rinka H, et al. Precision and Safety of an Intravascular Temperature Management System for Postcardiac Arrest Syndrome Patients: A Multicenter Clinical Trial (COOL-ARREST JP). Ther Hypothermia Temp Manag. 2020 Sep 1;10(3):179-85.

- ¹⁶ Heard KJ, Peberdy MA, Sayre MR, Sanders A, Geocadin RG, Dixon SR, et al. A randomized controlled trial comparing the Arctic Sun to standard cooling for induction of hypothermia after cardiac arrest. Resuscitation. 2010 Jan;81(1):9-14.
- ¹⁷ Glover GW, Thomas RM, Vamvakas G, Al-Subaie N, Cranshaw J, Walden A, et al. Intravascular versus surface cooling for targeted temperature management after out-of-hospital cardiac arrest - an analysis of the TTM trial data. Crit Care. 2016 Dec; 20(1):381.
- ¹⁸ Tømte Ø, Drægni T, Mangschau A, Jacobsen D, Auestad B, Sunde K. A comparison of intravascular and surface cooling techniques in comatose cardiac arrest survivors. Crit Care Med. 2011 Mar;39(3):443-9.
- ¹⁹ Lord AS, Karinja S, Lantigua H, Carpenter A, Schmidt JM, Claassen J, et al. Therapeutic Temperature Modulation for Fever After Intracerebral Hemorrhage. Neurocrit Care. 2014 Oct;21(2):200-6.
- ²⁰ Carhuapoma JR, Gupta K, Coplin WM, Muddassir SM, Meratee MM. Treatment of Refractory Fever in the Neurosciences Critical Care Unit Using a Novel, Water-Circulating Cooling Device: A Single-Center Pilot Experience. J Neurosurg Anesthesiol. 2003 Oct: 15(4): 313-8.
- ²¹ Våga A, Busch M, Karlsen TE, Nilsen OB, Søreide E. A pilot study of key nursing aspects with different cooling methods and devices in the ICU. Resuscitation. 2008 Jan;76(1):25-30.
- ²² Merchant RM, Abella BS, Peberdy MA, Soar J, Ong MEH, Schmidt GA, et al. Therapeutic hypothermia after cardiac arrest: unintentional overcooling is common using ice packs and conventional cooling blankets. Crit Care Med. 2006 Dec;34(12 Suppl):S490-494.
- ²³ Medivance. Arctic Sun® Energy Transfer PadTM Instructions for Use.
- ²⁴ Varon J, Acosta P. Therapeutic hypothermia: past, present, and future. Chest. 2008 May; 133(5): 1267-74.
- ²⁵ Wang HE, Wells JM, Rizk DV. Bullous Lesions After Use of a Commercial Therapeutic Hypothermia Temperature Management System: A Possible Burn Injury? Ther Hypothermia Temp Manag. 2013 Sep;3(3):147-50.
- ²⁶ Liu YM, Ibrahim A, Jan T, Chang P, Fagan S, Goverman J. Skin Necrosis as a Complication of Therapeutic Hypothermia: J Burn Care Res. 2014;35(3):e184-6.
- ²⁷ RECCLAIM-II REperfusion With Cooling in Cerebral Acute IscheMia II (Identifier: NCT03804060). ClinicalTrials.gov
- $^{\rm 28}\, \rm COOL$ AMI EU Pivotal Trial to Assess Cooling as an Adjunctive Therapy to PCI In Patients With Acute MI (Phase A) (Identifier: NCT03173313). ClinicalTrials.gov
- ²⁹ Knapik P, Rychlik W, Siedy J, Nadziakiewicz P, Cie\(\mathbb{D}\)la D. Comparison of intravascular and conventional hypothermia after cardiac arrest. Kardiol Pol. 2011;69(11):1157-63.
- $^{\rm 30}\,\mbox{Bray JE},\,\mbox{Stub D, Bloom JE, Segan L, Mitra B, Smith K, et al.}$ Changing target temperature from 33°C to 36°C in the ICU management of out-of-hospital cardiac arrest: A before and after study. Resuscitation. 2017;113:39-43.
- ³¹ZOLL Medical Corporation. Quattro Catheter Kit Instructions for Use 106142-001 Rev 5.
- ³² Yaghoubi M, Javanbakht M, Mashayekhi A, Hemami MR, Branagan-Harris M, Keeble TR. Cost-Effectiveness Analysis of Intravascular Temperature Management after Cardiac Arrest in England.; 2021:2021.08.16.21262120. doi:10.1101/2 021.08.16.21262120
- 33 SGS Institut Fresenius GmbH, ZOLL Medical Deutschland GmbH. Corporate Carbon Footprint 2018 & 2019 - ZOLL Medical EMEA. 2021.
- 34 Taccone FS, Picetti E, Vincent J-L. High Quality Targeted Temperature Management (TTM) After Cardiac Arrest. Crit Care Lond Engl. 2020 Jan 6;24(1):6.

ZOLL MEDICAL CORPORATION

269 Mill Road | Chelmsford, MA 01824 | 978-421-9655 | zoll.com

and ZOIL are trademarks or registered trademarks of ZOIL Medical Corporation in the United States and/or other countries. All other

For subsidiary addresses and

fax numbers, as well as other global locations, please go to

zoll.com/contacts.